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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,392	08/13/2001	Theodore E. Spielberg	15343-0028C3	6911

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EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/19/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,392

Applicant(s)

SPIELBERG, THEODORE E.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 11-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☒ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

Re: Spielberg, T.

Date of Priority: May 20, 1994

The Amendment filed September 19, 2003 in response to the Notice of Non-responsiveness is acknowledged and has been entered.

Claims 1-4, 6-8, 11-13, 15-17 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

The corrected drawing (Fig. 4A) was received on 06-02-03. This drawings is acceptable.

Election/Restrictions

Newly submitted/amended claim 1 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 1 no longer requires that the claimed microdisk comprise encapsulated endocrine cells. Thus, Claim 1, and dependents thereof, are broader than the originally elected invention and would have been restricted from the presently elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, claims 1-4, and 6-8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Maintained:

Claims 11-13 remain as being anticipated by Yang *et al.* (Biomaterials, January 1994, Vol. 15(2): 113-120.) for the reasons of record. Applicants argue (Paper No. 8, page 6) that Yang *et al.* is not prior art under 35 USC 102(b) because the present application is accorded priority to May 20, 1994. However, since the Yang *et al.* reference is, in fact, prior art by another preceding the May 20, 1994, the reference is prior art under 35 USC 102(a). Applicants further argue (page 6) that there is nothing in the Yang *et al.* reference to suggest inherency of the claimed invention. Applicants add that the mere fact that the prior art could be so modified would not make the modification obvious unless the prior art suggested the desirability of the modifications. These arguments have been carefully considered but are not found persuasive for the reasons of record. As set forth previously, the specification does not clearly define the limitations of the geometric shapes of the claimed microdisk. The specification only generally teaches (page 8) how the concave shapes may be formed. For example, if the interior cavity of the disks are not completely filled with cellular and related material, one or more of the opposed faces, when formed of sufficiently thin and pliable material, *will conform itself* generally to the surface of its liquid contents, assuming at least a "saucer" shape. On the other hand, if the faces of the disk are of sufficient thickness and strength, the disk may be molded with the concavity formed in place. Thus, inherently, the discs of Yang *et al.* have at least one concave face or two opposed concave faces maintained by internal joining structure and can generally form the shape of an erythrocyte.

New Objections:

Claims 15-17 are objected to as being dependent upon a rejected base claim.

No claim is allowed.

Conclusion

Applicant's amendment/arguments necessitated the new ground(s) of rejection/objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GARY NICKOL
PRIMARY EXAMINER

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN
March 16, 2004

